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Filed : November 13, 2003

## REMARKS

The first paragraph of the specification is amended to clarify the statutory basis for claiming priority to PCT application US03/15493.

Claims 109-145 and 197-215 are currently pending. Claims 1-108 and 146-196 are canceled. Applicants reserve their right to pursue the subject matter of any or all of these claims in one or more continuing applications.

Claims 109 and 142 are amended. Claims 213-215 are newly added. Support for the amendment to claim 109 can be found at page 168, in Table 18 and elsewhere throughout the specification. Support for newly added claims 213, 214 and 215 can be found at page 206, in Table 33 and at page 222, lines 4-19 (for example, SEQ ID NO: 891 has two mismatches with respect to SEQ ID NO: 3 in the range of nucleotides 3249-3268); at page 151, in Table 12 (for example, SEQ ID NO: 319 has one mismatch with respect to SEQ ID NO: 3 in the range of nucleotides 3249-3268); and at page 218, in Table 41, respectively. As such, no new matter has been added by way of these new claims or amendments.

Reconsideration of the pending claims in view of the amendments and remarks presented herein is respectfully requested.

### Response to Rejection under 35 U.S.C. § 112, first paragraph

The Examiner rejects claims 109-124 under 35 U.S.C. § 112, first paragraph as “failing to comply with the written description requirement.” In particular, the Examiner states that the specification does not provide support for antisense sequences comprising two mismatches with respect to SEQ ID NO: 3 that specifically hybridize beyond the range of nucleotides 3249-3268; however, the specification does provide support for antisense compounds “wherein said mismatches are within the nucleotide sequence of 3249-3268 of SEQ ID NO: 3.”

As discussed during the interview of December 12, 2006, Applicants have agreed to amend independent claim 109 to recite the phrase “wherein said mismatches are within the nucleotide sequence of 3249-3268 of SEQ ID NO: 3.” The Examiner has indicated that such amendment would overcome the above-described rejection of independent claim 109 and the claims dependent thereon. Accordingly, in view of the amendment to claim 109, Applicants

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respectfully request that the Examiner withdraw the rejection of claims 109-124 under 35 U.S.C. § 112, first paragraph.

Response to Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejects claims 142-145 under 35 U.S.C. § 112, second paragraph as “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In particular, the Examiner asserts that it is unclear whether the phrase “having *a sequence* of nucleobases as set forth in SEQ ID NO: 247” is intended to limit the claimed antisense oligonucleotide to the full-length sequence of SEQ ID NO: 247 or whether the phrase is intended to limit the claimed antisense oligonucleotide to comprise a fragment of SEQ ID NO: 247.

Applicants maintain that the phrase “having a sequence of nucleobases as set forth in SEQ ID NO: 247” is clear; however, in order to expedite the allowance of claims 142-145, Applicants have amended independent claim 142 to recite the phrase “having the sequence of nucleobases as set forth in SEQ ID NO: 247.” As agreed during the interview of December 12, 2006, such amendment would overcome the instant indefiniteness rejection. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claims 142-145 under 35 U.S.C. § 112, second paragraph.

Response to Rejection under 35 U.S.C. § 102(b)

The Examiner rejects claims 142-145 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,172,216 (Bennett et al.). In particular, the Examiner asserts that Bennett et al. disclose an antisense oligonucleotide that comprises 13 identical nucleobases with respect to SEQ ID NO: 247 and that comprises a region of 9 contiguous nucleobases that are 100% complementary to nucleobases 3258-3268 of SEQ ID NO: 3. Additionally, the Examiner asserts that Bennett et al. disclose such oligonucleotides having phosphorothioate linkages and 2’MOE modifications at nucleobase positions 1-5 and 16-20, wherein all of the 2’MOE cytosines are 5-methylcytosines.

Applicants respectfully disagree, however, in order to expedite the allowance of claims 142-145, Applicants have amended independent claim 142 as indicated above. In particular,

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Applicants have amended independent claim 142 to replace the phrase “having a sequence of nucleobases as set forth in SEQ ID NO: 247” with “having the sequence of nucleobases as set forth in SEQ ID NO: 247.” As agreed in the interview of December 12, 2006, Bennett et al. do not disclose or suggest an antisense oligonucleotide 20 nucleobases in length having the nucleobase sequence of SEQ ID NO: 247. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claims 142-145 under 35 U.S.C. § 102(b).

**Response to Obviousness Type Double Patenting Rejection**

The Examiner provisionally rejects claims 109-145 and claims 197-212 under the judicially created doctrine of obviousness-type double patenting. In particular, the Examiner asserts that these claims are obvious over claims 1-34 of copending U.S. Patent Application No. 10/920,612 (the ‘612 application) or are obvious over claims 1-34 of the ‘612 application in view of Bennett et al.

Applicants maintain that claims 109-145 and claims 197-212 are neither obvious over claims 1-34 of the ‘612 application nor obvious over claims 1-34 of the ‘612 application in view of Bennett et al. Applicants would like to point out that in an amendment filed January 8, 2007, claims 1-34 of the ‘612 application have been amended to recite antisense oligonucleotides that specifically hybridize to a region of SEQ ID NO: 3 that is more than 2000 nucleobases downstream of the regions of SEQ ID NO: 3 recited in the instant claims. As such, the claims of the instant application are not obvious over ‘612 application either alone or in combination with Bennett et al.

In addition to the foregoing, Applicants note that M.P.E.P. § 804(I)(B)(1) states that “[i]f a ‘provisional’ nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.” Applicants respectfully submit that the instant application was filed prior to the filing of the ‘612 application. As such, in accordance with section 804 of the M.P.E.P., the provisional obviousness-type double patenting rejection should not be maintained provided that claims 109-145 and claims 197-215 are otherwise allowable.

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In view of the foregoing remarks, Applicants respectfully request that the Examiner withdraw the provisional obviousness-type double patenting rejection of claims 109-145 and 197-215.

### **CONCLUSION**

Applicants believe that all outstanding issues in this case have been resolved and that the present claims are in condition for allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact the undersigned at the telephone number provided below in order to expedite the resolution of such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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